

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

CELGENE CORP.,

Plaintiff,

V.

BARR LABORATORIES, INC. and
BARR PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 07-286 (PGS)

Hon. Peter G. Sheridan

Magistrate Judge Ronald J. Hedges

Return Date: March 26, 2007

Oral Argument Requested

**BRIEF IN SUPPORT OF DEFENDANT
BARR PHARMACEUTICALS, INC.'S
MOTION TO DISMISS THE COMPLAINT**

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INTRODUCTION

Barr Pharmaceuticals is not a proper party to this action. There is only one act of infringement alleged in Celgene's complaint – the “highly artificial act of infringement” under 35 U.S.C. § 271(e)(2) of submitting a generic drug application that challenges patents connected to the brand name drug. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1349 (Fed. Cir. 2004). Barr Laboratories, Inc., not Barr Pharmaceuticals, submitted the application. By statute, only Barr Laboratories has engaged in this technical act of infringement under § 271(e)(2). Thus, Barr Pharmaceuticals has not directly infringed the patents Celgene asserts in this suit. Moreover, Celgene cannot state a claim against Barr Pharmaceuticals for inducing infringement on the theory that Barr Pharmaceuticals induced Barr Laboratories to file the application. There is no cognizable cause of action for inducing an ANDA filing. This Court should dismiss Celgene's complaint against Barr Pharmaceuticals.

BACKGROUND

I. Statutory Background.

Celgene's case is grounded in the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (“FFDCA”). *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Under the FFDCA, as amended, a company seeking approval to market a drug that has not previously been approved must file with the U.S. Food and Drug

Administration (“FDA”) a New Drug Application (“NDA”) which contains studies showing the proposed drug product is safe and effective. 21 U.S.C. § 355(b)(1). The NDA must include, among other things, any patent that claims the drug or a method of using the drug. *Id.* FDA publishes the patent information in connection with the NDA in “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” 21 U.S.C. § 355(b)(1), -(j)(7)(A)(iii).

A company seeking approval of a generic version of an already approved NDA drug may file an ANDA that relies on the safety and efficacy studies performed on the NDA drug. *Id.* § 355(j)(1)-(2). To do so, the ANDA applicant must, among other things, submit a “certification” for each patent listed in the Orange Book in connection with the NDA drug. *Id.* § 355(j)(2)(A)(vii). An ANDA applicant seeking to obtain approval prior to expiration of a listed patent must (with certain exceptions) submit a “paragraph IV” certification, which states that the patent is invalid, unenforceable and/or will not be infringed by the proposed ANDA product. *Id.* § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

The submission of an ANDA with a paragraph IV certification constitutes technical infringement under 35 U.S.C. § 271(e)(2), but it is a unique kind of “infringement.” It is a “highly artificial act of infringement,” “the very

limited and technical purpose” of which is “to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue.” *Glaxo*, 376 F.3d at 1349, 1351 (citing and quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 678 (1990)). The Federal Circuit thus considers § 271(e)(2) “to be primarily a jurisdictional-conferring statute that establishes a case or controversy in a declaratory judgment action.” *Glaxo*, 376 F.3d at 1351. “[T]he patentee’s burden of proving ultimate infringement is not met by the filing of the ANDA.” *Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997). Rather, the court must determine “whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product,” based on “[w]hat is likely to be sold, or, preferably, what will be sold” following FDA approval. *Id.*

Section 271(e)(2) is also unique because only a limited number of remedies are available to a patentee that proves its infringement claims pursuant to § 271(e)(2). Before FDA approval, when the ANDA applicant has not engaged in commercial manufacture, use or sale of the patented product, the court may only order that the effective date of FDA approval be delayed until patent expiration and enjoin any future manufacture, use or sale by the ANDA applicant.¹ 35 U.S.C.

¹ In limited circumstances, only where the ANDA applicant has made a baseless paragraph IV certification and engaged in litigation misconduct, the court may also award attorneys’ fees. *Glaxo*, 376 F.3d at 1349-51.

§ 271(e)(4) (listed remedies “are the only remedies which may be granted by a court for an act of infringement described in [§ 271(e)](2)”).

II. Factual Background.

Celgene holds approved NDA No. 20-785 for Thalomid[®], known generically as thalidomide. (Compl. ¶ 19.) Celgene listed several patents in the Orange Book in connection with NDA No. 20-785, including the patents Celgene asserts against Barr Laboratories and Barr Pharmaceuticals here. (*Id.* ¶ 20.)

In 2006, Barr Laboratories filed ANDA No. 78-505, seeking approval to market a generic version of Thalomid[®]. (*Id.* ¶ 21.) Barr Laboratories’ ANDA contains paragraph IV certifications to the patents Celgene asserts. (*Id.* ¶ 22.) Barr Laboratories duly notified Celgene of its paragraph IV certifications in December 2006. (*Id.* ¶ 23.) Celgene thereafter initiated this lawsuit against Barr Laboratories, asserting infringement claims under § 271(e)(2). (*Id.* ¶¶ 25-73.)

Celgene also included Barr Pharmaceuticals as a party. Celgene’s only allegations specifically pertaining to Barr Pharmaceuticals are that Barr Laboratories is a subsidiary of Barr Pharmaceuticals (*id.* ¶ 5) and that “[o]n information and belief, the acts of Barr Laboratories, Inc. complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, Barr Pharmaceuticals, Inc.” (*id.* ¶ 7). From these bare allegations, Celgene seeks to

leverage infringement claims against Barr Pharmaceuticals, despite the fact that Celgene has made no allegation that Barr Pharmaceuticals actually submitted the ANDA or committed any act of infringement cognizable under § 271(e)(2).

ARGUMENT

I. Legal Standards.

When deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court “should look to the face of the complaint and decide whether, taking all of the allegations of fact as true and construing them in a light most favorable to the nonmovant, plaintiff’s allegations state a legal claim.” *NN&R, Inc. v. One Beacon Ins. Group*, 362 F. Supp. 2d 514, 518 (D.N.J. 2005). The Court, however, is “not required to credit bald assertions or legal conclusions alleged in the complaint.” *Jones v. Intelli-Check, Inc.*, 274 F. Supp. 2d 615, 625 (D.N.J. 2003). “Similarly, legal conclusions draped in the guise of factual allegations do not benefit from the presumption of truthfulness.” *Id.* Thus, when ruling on a motion under Rule 12(b)(6), “courts can and should reject ‘legal conclusions,’ ‘unsupported conclusions,’ ‘unwarranted references,’ ‘unwarranted deductions,’ ‘footless conclusions of law,’ and ‘sweeping legal conclusions in the form of actual allegations.’” *Perry v. Gold & Laine, P.C.*, 371 F. Supp. 2d 622, 626 (D.N.J. 2005) (quoting *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 907 n.8 (3d Cir. 1997)).

II. Celgene Has Failed To State A Claim Against Barr Pharmaceuticals For Direct Infringement.

Celgene has not stated a claim against Barr Pharmaceuticals for directly infringing the patents Celgene asserts. Accordingly, Celgene's direct infringement claims against Barr Pharmaceuticals must be dismissed.

A. Barr Pharmaceuticals Did Not Submit The ANDA.

Through the Hatch-Waxman Act, Congress expressly provided that a generic drug maker's pre-launch activities in furtherance of its application for regulatory approval do not constitute patent infringement: "It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" 35 U.S.C. § 271(e)(1). This safe harbor prevents a branded drug maker from suing an ANDA applicant for infringement for any activities related to developing its generic product. *See Eli Lilly*, 496 U.S. at 678 (observing that § 271(e)(1) "disable[s]" a patent holder from establishing there has been an act of infringement).

There is one exception to the § 271(e)(1) safe harbor, and it is found in § 271(e)(2). Under § 271(e)(2), a patentee may sue an ANDA applicant when, and only when, the applicant submits the ANDA and seeks approval before the expiration of the listed patents. *See* 35 U.S.C. § 271(e)(2)(A). The sole "act of

infringement” under § 271(e)(2)(A) is the “submi[ssion]” of an ANDA with a paragraph IV certification. Thus, a party that does not “submit” the ANDA does not commit the technical act of infringement required for purposes of § 271(e)(2)(A). *See SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 287 F. Supp. 2d 576, 584 (E.D. Pa. 2002) (“By its terms, the Act limits liability for direct infringement to the party submitting the ANDA.”); *SmithKline Beecham Corp. v. Pentech Pharms., Inc.*, No. 00 C 2855, 2001 WL 184804, at *2 (N.D. Ill. Feb. 20, 2001) (“The plain language of the statute controls. . . . Section 271(e)(2)(A) unambiguously refers only to persons who submit ANDAs.”) (Ex. 1).²

Here, it was Barr Laboratories, and no other company, that submitted the relevant ANDA. (*See* Compl. ¶ 1 (action allegedly arises from “Barr Laboratories, Inc.’s filing” of thalidomide ANDA); Ex. 2 (cover letter to ANDA No. 78-505)³.) Therefore, even if the allegation that Barr Pharmaceuticals assisted Barr Laboratories in submitting the application was true, Plaintiffs do not (and

² “Ex. __” refers to Exhibits 1-4 attached to the Declaration of Lindsey H. Taylor in Support of Defendant Barr Pharmaceuticals, Inc.’s Motion to Dismiss the Complaint.

³ On a Rule 12(b)(6) motion to dismiss, the Court is permitted to consider documents that are “integral to or explicitly relied upon in the complaint.” *Angstadt v. Midd-West Sch. Dist.*, 377 F.3d 338, 342 (3d Cir. 2004) (quotations omitted). Barr Laboratories’ thalidomide ANDA is explicitly relied upon in Celgene’s complaint. (*See, e.g.*, Compl. ¶¶ 1, 21-73.) Moreover, it is integral to the complaint because it provides the basis for Celgene’s infringement claims under § 271(e)(2).

cannot) allege that Barr Pharmaceuticals engaged in the only act that constitutes technical infringement – the submission of the ANDA. *See Geneva*, 287 F. Supp. 2d at 584 (holding that only the company that submitted the ANDA could be held liable as direct infringer under § 271(e)(2)); *Pentech*, 2001 WL 184804, at *2 (same).

B. Celgene Has Not Alleged Facts Sufficient To Hold Barr Pharmaceuticals Vicariously Liable For Barr Laboratories' ANDA Submission.

Celgene has not alleged any facts that would allow this Court to impose vicarious liability for direct infringement on Barr Pharmaceuticals based on Barr Laboratories' submission of the ANDA. Simply put, Celgene has not alleged any facts that would warrant disregarding Barr Pharmaceuticals' or Barr Laboratories' distinct corporate statuses.

Parent companies generally are not liable for the acts of their subsidiaries. *United States v. Bestfoods*, 524 U.S. 51, 61 (1998). Accordingly, courts, including the Federal Circuit, have repeatedly held in the patent context that a parent company may be held liable for the allegedly infringing acts of its subsidiary “only if the evidence reveals circumstances justifying disregard of the status of [the parent and subsidiary] as distinct, separate corporations.” *A. Stucki Co. v. Worthington Indus., Inc.*, 849 F.2d 593, 596 (Fed. Cir. 1988); accord *Ronald A. Katz Tech. Licensing, L.P. v. Verizon Comms., Inc.*, No. Civ. A. 01-5627, 2002

WL 31834833, at *2 (E.D. Pa. Dec. 18, 2002) (refusing to impose infringement liability on parent holding company for subsidiary's infringement because patentee had not shown facts sufficient to pierce the corporate veil) (Ex. 3) (citing *Bestfoods*, 524 U.S. at 62).⁴

Celgene has not alleged any fraud or inequity in Barr Pharmaceuticals' or Barr Laboratories' corporate forms. Nor has Celgene alleged that Barr Pharmaceuticals exercises complete domination and control over Barr Laboratories sufficient to deem Barr Laboratories the alter ego of Barr Pharmaceuticals. Thus, Celgene has not alleged any facts that would permit this Court to disregard Barr Pharmaceuticals' or Barr Laboratories' corporate statuses and pierce the corporate veil. *See Grasty v. Michail*, No. Civ. A. 02C-05-89 CLS, 2004 WL 396388, at *2 (Del. Super. Feb. 24, 2004) (parent's funding and control of certain actions of subsidiary are insufficient to pierce corporate veil under Delaware law) (Ex. 4); *Cencom Cable Income Partners v. Wood*, 752 A.2d 1175, 1184 (Del. Ch. 1999) (parent must exercise "exclusive domination and control . . . to the point that [the subsidiary] no longer ha[s] independent significance" to pierce corporate veil under Delaware law).

⁴ *Cf. Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1331 (Fed. Cir. 1999) (holding that officer may only be liable for corporation's alleged patent infringement upon showing that corporate veil should be pierced); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990) (same).

Accordingly, Barr Pharmaceuticals cannot be held vicariously liable for Barr Laboratories' submission of the ANDA. This Court should dismiss Celgene's claims against Barr Pharmaceuticals to the extent Celgene is alleging that Barr Pharmaceuticals directly infringed the patents Celgene has asserted.

III. Celgene Has Failed To State A Claim Against Barr Pharmaceuticals For Inducing Infringement.

This Court should also dismiss Celgene's claims against Barr Pharmaceuticals in Count VIII of the complaint for inducing infringement under 35 U.S.C. § 271(b).

A. There Is No Cause Of Action For Inducing The Filing Of A Paragraph IV ANDA.

Inducing infringement under § 271(b) requires proof of both an affirmative act that causes, urges, encourages, or aids another to directly infringe and specific intent to infringe the patent. *See Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1378-79 (Fed. Cir. 2001) (inducement "requires an affirmative act of some kind"); *Warner Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) ("[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven."). In addition, the patentee must prove the patent was, in fact, directly infringed as a result. *E-Pass Techs., Inc. v. 3Com Corp.*, 473 F.3d 1213, 1221-22 (Fed. Cir. 2007).

While the Federal Circuit has stated that inducement claims are available under § 271(e)(2), those claims are focused on whether the ANDA applicant itself will induce infringement through the future marketing of the ANDA product. *See Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003). The Federal Circuit has never held that inducement claims may be sustained for a third party's inducement of the filing of an ANDA. Several district courts have addressed the issue, however, and have concluded that they may not. *See Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 321 F. Supp. 2d 612, 616 (D. Del. 2004) (“[A] claim for inducement of infringement cannot be based solely upon allegations that a defendant aided and abetted the filing of an ANDA.”); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 267 F. Supp. 2d 545, 548-49 (N.D. W. Va. 2003) (dismissing claims for inducement of filing an ANDA); *AstraZeneca AB v. Mylan Labs., Inc.*, 265 F. Supp. 2d 213, 217 (S.D.N.Y. 2003) (“[W]hether the submission of an ANDA was induced is not the proper subject of a Hatch-Waxman action.”).⁵

⁵ Other courts have allowed such claims to proceed. *See, e.g., Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 450 F. Supp. 2d 757, 761-62 (E.D. Mich. 2006); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 495 (E.D. Va. 2005); *Geneva*, 287 F. Supp. 2d at 585-86; *Pentech*, 2001 WL 184804, at *3. In *Novo Nordisk*, however, the court found that the defendants' relationship as alleged could warrant piercing the corporate veil and expressly declined to decide “whether an entity which did not file the ANDA can be liable for inducement of infringement” under § 271(e)(2). *See Novo Nordisk*, 450 F. Supp. 2d at 761-62 (declining to resolve the question because patentee adequately alleged piercing the

These courts correctly recognize the unique and “highly artificial” nature of the § 271(e)(2) act of infringement and that the proper focus in § 271(e)(2) cases is on the ANDA product rather than the ANDA filing. *See AstraZeneca*, 265 F. Supp. 2d at 217 (“[T]he inquiry is properly focused on the ANDA product, not the ANDA filing.”); *Pfizer*, 321 F. Supp. 2d at 616-17 (same); *Ortho-McNeil*, 267 F. Supp. 2d at 548-49 (examining remedies for infringement under § 271(e)(2) and concluding that they apply to the ANDA product). Indeed, the structure of the Hatch-Waxman Act makes clear that inducement claims based on the act of filing a paragraph IV ANDA should not be permitted.

First, as discussed, actions taken to prepare for an ANDA filing are expressly exempt from patent infringement liability. 35 U.S.C. § 271(e)(1). The only exception to this safe harbor is in § 271(e)(2), which provides for a statutory act of infringement based on the ANDA submission. To allow inducement claims to proceed against a third party based solely on its assistance in filing the ANDA

corporate veil agency theory). The remaining cases failed to take into account the Federal Circuit’s more recent pronouncements regarding the unique “artificial” and largely jurisdictional nature of infringement under § 271(e)(2), as well as the statutory structure of Hatch Waxman. *See, e.g., Glaxo*, 376 F.3d at 1351 (disallowing claims of willful infringement based on paragraph IV ANDA filing because a finding of willfulness was not properly rested “on such a special-purpose peg” as § 271(e)(2)); *see also Allergan*, 324 F.3d at 1334 n.9 (rejecting patentee’s argument that liability for infringement attaches based simply on the filing of the ANDA); *Warner-Lambert*, 316 F.3d at 1365 (rejecting patentee’s argument that ANDA filing itself represents an act of infringement, relieving the patentee from establishing inducement factors, because “§ 271(e)(2)(A) simply provides an ‘artificial’ act of infringement”); *see infra* at pp. 12-13.

would constitute an end run around the safe harbor for such activities set forth in § 271(e)(1). *See Pfizer*, 321 F. Supp. 2d at 618 (“To allow one to be liable for inducement of infringement based solely on activities related to the preparation of the ANDA filing would undercut Section 271(e)(1)”); *AstraZeneca*, 265 F. Supp. 2d at 218 (same).

Second, the only remedies for an act of infringement under § 271(e)(2) are set forth in 35 U.S.C. § 271(e)(4). Section 271(e)(4), notably, does not provide a remedy to prevent or enjoin a party’s assistance in the filing of an ANDA. *See AstraZeneca*, 265 F. Supp. 2d at 218. And that is the only relief that Celgene could possibly seek against Barr Pharmaceuticals, since Barr Pharmaceuticals does not seek and will not have FDA approval to market the ANDA product. Barr Laboratories will.⁶

In sum, Celgene has only alleged that Barr Pharmaceuticals induced “the acts of Barr Laboratories, Inc. complained of herein,” namely, the submission of ANDA No. 78-505 seeking approval for Barr Laboratories to make, use and sell a thalidomide product. Celgene cannot state a claim for inducing the highly

⁶ To the extent Celgene might suggest that Barr Pharmaceuticals will induce infringement by assisting Barr Laboratories in making, using, or selling the product upon FDA approval, Celgene has not made any such allegation. Nor would such a speculative inducement claim be cognizable even if Celgene had made such an allegation. *See Warner-Lambert*, 316 F.3d at 1364-65 (“Section 271(e)(2) does not encompass ‘speculative’ claims of infringement. . . . That a generic maker may someday induce someone to infringe can only be determined when that act occurs, and § 271(e)(2) was not designed to cover such future acts.”).

artificial act of § 271(e)(2) infringement as a matter of law. Accordingly, this Court should dismiss Celgene's claims against Barr Pharmaceuticals for inducing infringement.

B. Celgene Has Failed To State A Claim For Inducement Under 35 U.S.C. § 271(b).

Finally, even if Celgene could state an inducement claim based on the filing of the ANDA, Celgene has failed to sufficiently allege that Barr Pharmaceuticals actually induced Barr Laboratories to file the ANDA.

Inducement under 35 U.S.C. § 271(b) requires proof of both specific intent and an affirmative act to induce infringement. *Warner-Lambert*, 316 F.3d at 1364. Celgene has failed to allege either. Nowhere does Celgene allege that Barr Pharmaceuticals specifically intended to induce Barr Laboratories' ANDA filing. Moreover, Celgene does not allege that Barr Pharmaceuticals engaged in an affirmative act of inducement.

Celgene only alleges that “[o]n information and belief, the acts of Barr Laboratories, Inc. complained of herein were done at the direction of, with the authorization of, *or* with the cooperation, participation, or assistance of, *or* at least in part for the benefit of, Barr Pharmaceuticals, Inc.” (Compl. ¶ 7 (emphasis added).) Accepting this allegation as true, if Barr Laboratories only filed the ANDA “with the authorization of” or “at least in part for the benefit of” Barr Pharmaceuticals, Barr Pharmaceuticals has not engaged in an affirmative act that

caused Barr Laboratories to submit the ANDA. Thus, the complaint fails to state a claim for inducing infringement. *See Tegal*, 248 F.3d at 1378-79 (holding that inducement claims cannot be based on inaction or omission to act and refusing to hold affiliate liable for inducing infringement by merely permitting commission of infringing acts); *A. Stucki*, 849 F.2d at 596-97 (same).

This Court should dismiss Celgene's inducement claim against Barr Pharmaceuticals for the independent reason that Celgene has not stated an inducement claim under 35 U.S.C. § 271(b).

CONCLUSION

Because Celgene does not and cannot state a claim for infringement against Barr Pharmaceuticals based on Barr Laboratories' ANDA filing, Barr Pharmaceuticals respectfully requests that this Court dismiss all of Celgene's claims against it, with prejudice.

Dated: March 1, 2007

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